IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	10/019,904	Confirmation No. 1012
Applicants	:	Victor John Yannacone, Jr. et al.	
Filed	:	May 6, 2002	
Title	:	METHOD AND APPARATUS FOR HIGH RESOLUTION DYNAMIC DIGITAL INFRARED IMAGING	
Art Unit	:	3737	
Examiner	:	Joel M. Lamprecht	
Customer No.	:	28289	

DECLARATION UNDER 37 C.F.R. § 1.131

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Victor John Yannacone, Jr. hereby declare as follows:

1.   Carol A. Yannacone, Benjamin A. Rousseau, Jacob Green, William B. Hobbins and I are the named inventors of the invention described and claimed in the above-captioned application. All right, title and interest in and to the application and the inventions and improvements therein disclosed have been assigned to me.

2.   The above-captioned application is the national stage of international application no. PCT/US00/16851, filed June 20, 2000, which claims priority from United States provisional patent application no. 60/140,128, filed June 21, 1999 (hereinafter "the '128 provisional application").

3.   Prior to October of 1998, I had a thermal image of an individual acquired as part of a process of correlating this thermal image with actual clinical data acquired from the individual. A copy of this thermal image acquired in accordance with the limitations of independent claims 1, 14, and 25, as amended in the Amendment filed with this Declaration, accompanies this Declaration as Exhibit A.

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4. More specifically, to acquire the accompanying thermal image, I had an IR imaging camera, configured to receive IR radiation from an array of optical elements (optels) in a field-of-view viewable by the IR imaging camera, operating under the control of a controller acquire plural frames of IR radiation from the individual positioned in a field-of-view of the IR imaging camera. Each frame was acquired during a corresponding frame sample interval, with each frame corresponding to the IR radiation acquired from the array of optels during its frame sample interval.

5. I then had a workstation determine plural rates of change as a function of the IR radiation acquired from the array, with each rate of change corresponding to a change of the IR radiation received from the same optel in at least two frames. The workstation then mapped each rate of change to a color (the original of the accompanying thermal image is in color). The workstation then mapped the color of each rate of change to a position in an image corresponding to the position of the corresponding optel in the field-of-view.

6. As can be seen from paragraphs 4 and 5 above, I had all of the limitations of independent claims 1, 14, and 25, as amended in the Amendment filed with this Declaration, performed prior to October of 1998.

7. Following the acquisition of the accompanying thermal image prior to October of 1998 and upon realizing the potential of the invention of independent claims 1, 14, and 25, as amended in the Amendment filed with this Declaration, to detect angiogenesis and angiogenic activity, I prepared a draft plan to further develop and prove the efficacy of said invention. This plan, prepared prior to October of 1998, included a list of activities to be taken in support of further development and proving the efficacy of said invention. A copy of these activities, titled "How it can be done...", accompanies this Declaration as Exhibit B.

8. As can be seen from the list, one of the activities was to "[g]raphically depict the rate of change of infrared radiative energy as a function of time for each site that has been previously identified as statistically significant by any protocol" (underline added). This activity was to be accomplished by way of, among other things, the method of steps (c)-(e) of independent claim 1.

9. The list also includes the activities: determining "the rate of change of infrared radiative energy (first derivative) as a function of time for each site... (see claim 4)"; determining "the acceleration of change (second derivative) of infrared radiative energy as a

function of time for each site... (see claim 4)", and "develop a common graphic presentation for all of the time domain data" (see e.g., claim 1, steps (d) and (e)).

10.   In pursuit of the activities of paragraphs 8 and 9 above between the time the accompanying thermal image was acquired prior to October of 1998 and the filing of the '128 provisional application, I correlated other thermal images acquired prior to October of 1998 in accordance with, among other things, the limitations of independent claims 1, 14, and 25 of the Amendment filed with this Declaration with actual clinical data acquired from the individuals associated with the thermal images.
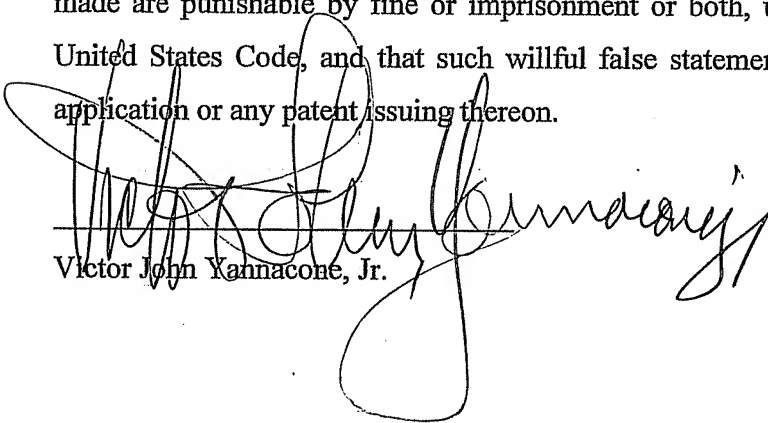
11.   Moreover, between the time the accompanying thermal image was acquired prior to October of 1998 and the filing of the '128 provisional application, I diligently conducted an ongoing investigation into the theory of the invention disclosed in the subject application and claimed in the claims of the Amendment filed with this Declaration in order to understand and refine the invention. This ongoing investigation included, without limitation, interviews of medical professionals and reviewing documents, such as medical, scientific and technical journals.

12.   During the period between the time the accompanying thermal image was produced prior to October of 1998 and the filing of the '128 provisional application, there was considerable uncertainty in the scientific and medical communities concerning mammalian thermoregulatory processes and the role of the sympathetic or autonomic nervous system in mediating or modulating such processes. It was during this period that the discovery of neoangiogenesis as the fundamental process of supplying blood to neoplastic lesions occurred and only in early 1999 was this discovery confirmed that neoangiogenic blood vessels supplying neoplastic lesions lacked any sympathetic nervous system control. This was the final element of the theoretical basis for the invention.

13.   Based on my understanding of the invention which I learned from my investigation, in or about the spring of 1999, I was in a position to fully explain the invention to patent counsel at the law firm of Webb, Ziesenheim, Logsdon, Orkin and Hanson, P.C. (now "The Webb Law Firm, P.C."). Thereafter, I reviewed a number of drafts of the provisional application identified in paragraph 2 above prepared by patent counsel prior to it being filed on June 21, 1999.

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14.   The aforementioned activity and conduct demonstrates the required evidence of conception, diligence and reduction to practice of the present invention.
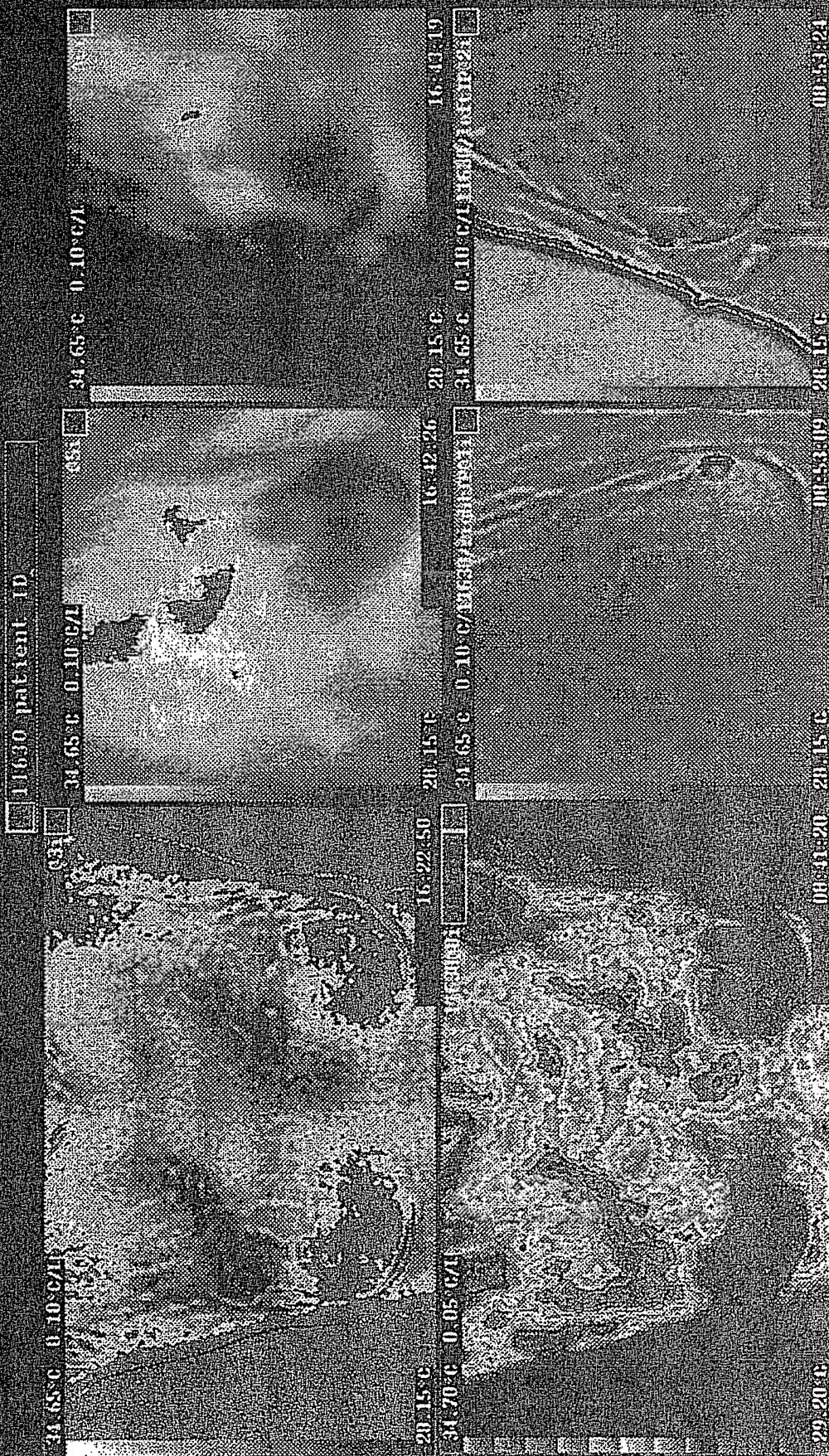
15.   I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

_____   16 June, 2009
Victor John Yannacone, Jr.   Date

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Exhibit A

How it can be done...

- Hire programmers with the appropriate skills and the commitment to round-the-clock effort.

- Take all the image data already available from which some kind of time series can be developed.

- Temporarily plan on a presentation page on which **image 1** is a plain multicolor infrared image of the body region before analysis. **Image 2** will be the soft tissue image showing structures such as blood vessels and nerves as well as tissue boundaries and other *anatomical* structures where they can be identified. **Image 3** will be the thermal anomaly image which, in the appropriate case may be combined or superimposed on Image 2 to save space. **Image 4** will be the comparison of structure boundaries with identification of statistically significant variations. **Image 5** will be the graphical presentation of the significant time domain data.

- Standardize a computer protocol (expert system...) for extracting the soft tissue information and preparing its image from the data.

- Standardize a computer protocol for identifying thermal anomalies in the data utilizing statistical techniques such as auto- and cross-correlation, discriminant and factor analysis in addition to conventional regressions and presenting the information in graphical and/or image form .

- Standardize a computer protocol for identifying soft tissue boundaries such as vessel walls or tissue discontinuities and then comparing infrared information from adjacent and comparable contralateral areas with the same statistical techniques utilized for identifying thermal anomalies and then presenting the information in graphical and or image form. *e.g.* red spots along the mammary vasculature.

- Graphically depict the rate of change of infrared radiative energy as a function of time for each site that has been previously identified as statistically significant by any protocol.

- Determine the rate of change of infrared radiative energy (first derivative) as a function of time for each site that has been previously identified as statistically significant.

- Determine the acceleration of change (second derivative) of infrared radiative energy as a function of time for each site that has been previously identified as statistically significant.

- Develop a common graphic presentation for all of the time domain data.

- Develop the operator interface in its simplest form with as little operator intervention required as possible. (Touch screen, single button, single keystroke combinations, ... anything that does not require a mouse.)

- Standardize the analysis presentation format and image presentation format.

- Keep Dr. Greene and Dr. Hobbins on line with a printer and telephone link so that they can discuss images and work on a continuous basis. Let them become positive and negative feedback loops.

- Immediately capture the essence of Dr. Hobbins in an expert system of differential diagnosis based on high resolution dynamic digital infrared imaging. Then proceed to Dr. Hooshman. . .

- Assure each expert whose essence we intend to capture some participation in the income derived from the intellectual property developed from them so long as they continue to support the system or until they die.